ISRCTN48289853 https://doi.org/10.1186/ISRCTN48289853

Effects of a combined treatment with Glucomannan and Garcinia cambogia on patients with obesity

Submission date
15/01/2018

Recruitment status
No longer recruiting

Registration date
17/01/2018

Overall study status
Completed

Last Edited
17/01/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary

Background and study aims
Overweight and obesity are considered major health problems that contribute to a reduction in quality of life and increase mortality (death) risk. Both conditions have a high prevalence across the world reaching epidemic numbers. Weight loss supplements are becoming popular as a weight to lose fat. Garcinia cambogia (GC) is a fruit that has an ingredient that might incresae weight loss. Glucomannan (GNN) is an ingredient derived from a plant that is also marketed for weight loss. The aim of this study is to evaluate the effects of the administration of Garcinia cambogia (GC) and Glucomannan (GNN) on long-term weight loss in people with overweight or obesity.

Who can participate?
Adults aged 18 and older who have a BMI over 25.

What does the study involve?
Participants have a balanced diet (Mediterranean diet), regular meals and intake of plenty of water. Standardised extracts of Garciania cambogia (52.4% Hydroxycitric acid) and Amorphophallus konjac (94.9%, Glucomannan) are administered separately in capsules of 500 mg each. Participants are treated with GC (500 mg), twice a day, half an hour before lunch and dinner and GNN (500 mg), twice a day, half an hour before lunch and dinner for six months. Participants are assessed for their weight and fat percentage.

What are the possible benefits and risks of participating?
Participants may benefit in improvements in their condition. There are no direct risks with participating.

Where is the study run from?
Scientifics Aesthetics Clinics of the body (Spain)

When is the study starting and how long is it expected to run for?
June 2014 to October 2017

Who is funding the study?
Universidad de Córdoba (Spain)

Who is the main contact?
Professor José L Lancho (Scientific)

Contact information

Type(s)
Scientific

Contact name
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14071

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GC/GNN-2

Study information

Scientific Title
Combined treatment of Garcinia cambogia and Glucomannan reduce weight, change body composition and ameliorate lipid and glucose blood profiles of people with overweight or obesity

Study hypothesis
Combined treatment reduces weight, changes body composition and ameliorate lipid and glucose blood profiles in overweight/obese patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethical Boards of Hospital Universitario Reina Sofia de Córdoba (Spain), 14/09/2014, ref: GC /GNN-2

Study design
Non randomized prospective trial evaluating differences between two dependent means (matches pairs design)

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available.

Condition
Obesity/overweight

Interventions
Participants have a balanced diet (Mediterranean diet), regular meals and intake of plenty of water. Standardised extracts of Garciania cambogia (52.4% Hydroxycitric acid) and Amorphophallus konjac (94.9%, Glucomannan) are administered separately in capsules of 500 mg each. Participants are treated with GC (500 mg), twice a day, half an hour before lunch and dinner and GNN (500 mg), twice a day, half an hour before lunch and dinner for six months.

Intervention Type
Supplement

Primary outcome measure
1. Weight is measured using digital balance (HD-305 TanitaTM) to the nearest 0.1 kg at baseline, three and six months of treatment
2. Fat mass is measured using a BioScan Spectrum operating at 50 KHz at baseline, three and six months of treatment
3. Visceral Fat mass is measured using the BioScan Spectrum operating at 50 KHz at baseline, three and six months of treatment

Secondary outcome measures
1. Glucose (mg/dl) is measured from blood samples using a colorimetric enzyme assay method (CEPA® kits – MBiolog Diagnósticos Ltda.) at baseline, three and six months of treatment
2. Tryglerides (mg/dl) is measured from blood samples using using a colorimetric enzyme assay method (CEPA® kits – MBiolog Diagnósticos Ltda.) at baseline, three and six months of

treatment
3. Cholesterol (mg/dl) is measured from blood samples using a colorimetric enzyme assay method (CEPA® kits – MBiolog Diagnósticos Ltda.) at baseline, three and six months of treatment

Overall study start date
01/06/2014

Overall study end date
01/10/2017

Eligibility

Participant inclusion criteria
1. Males and females
2. Aged 18 years old
3. Have an BMI>25

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
135

Participant exclusion criteria
1. Pregnancy or lactation
2. Gastroplasty or gastrointestinal weight-reducing surgery
3. Stopped smoking during the past 6 months
4. Kidney disease
5. History of recurrent kidney stones
6. Liver dysfunction
7. Untreated high blood pressure
8. History or symptoms of gallstones
9. Cancer
10. History of endocrine disorders (particularly hypothyroidism)
11. History of bulimia and/or laxative abuse
12. Mental disorders with impaired independence
13. History of alcohol or other drug abuse

Recruitment start date
08/01/2015

Recruitment end date
08/01/2017

Locations

Countries of recruitment
Spain

Study participating centre
Scientifics Aesthetics Clinics of the body
Avda. Periodista quesada Chacon numero 1
Cordoba
Spain
14071

Sponsor information

Organisation
University of Córdoba

Sponsor details
Department of Morphological Sciences
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Avenida de Menéndez Pidal s/n 14071
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14071

Sponsor type
University/education

ROR
https://ror.org/05yc77b46

Funder(s)

Funder type
University/education

Funder Name
Universidad de Córdoba

Results and Publications

Publication and dissemination plan
Planned submission to peer review evaluation to BMC pharmacology and toxicology.

Intention to publish date
01/04/2018

Individual participant data (IPD) sharing plan
In order to comply with Spanish law we can not describe this information unless a writing consent from each patient has been signed.

IPD sharing plan summary
Not expected to be made available